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(54) **LASER TISSUE ABLATION SYSTEM**

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(51) **Int. Cl.**

A61B 18/18 (2006.01)
A61B 18/22 (2006.01)

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(52) **U.S. Cl.**

CPC ***A61B 18/22*** (2013.01); *A61B 18/24* (2013.01); *A61B 2017/4216* (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61B 2018/00559; A61B 18/24; A61B 2017/4216; A61B 2018/0022; A61B 2018/1861

USPC 606/13–15

See application file for complete search history.

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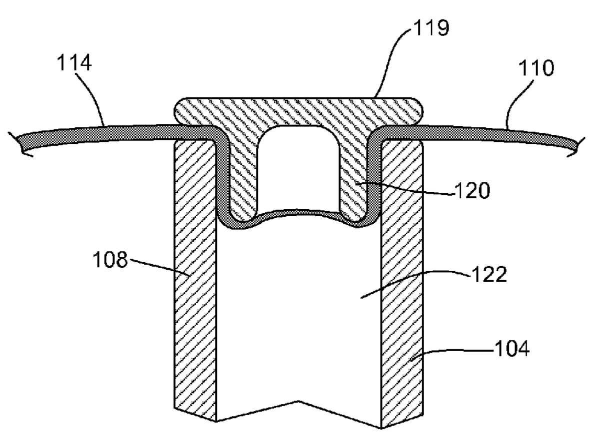
(57) **ABSTRACT**

Embodiments of a laser ablation system include a shaft, a balloon and a laser fiber. The shaft has a proximal end and a distal end. The balloon is attached to the distal end of the shaft, a portion of which is disposed within the balloon. A light dispenser at a distal end of the laser fiber is configured to deliver laser light through the balloon. A central axis of the balloon is aligned with a longitudinal axis of the shaft. The balloon has a variable transparency such that the transmission of laser light through the balloon is non-uniform along the central axis. Accordingly, an energy of laser light transmitted from the light dispenser through the balloon to the targeted tissue varies due to the variable transparency of the balloon.

15 Claims, 10 Drawing Sheets



(51) **Int. Cl.**

A61B 18/24	(2006.01)
A61B 17/42	(2006.01)
A61B 18/00	(2006.01)

(52) **U.S. Cl.**

CPC *A61B 2018/0022* (2013.01); *A61B 2018/00196* (2013.01); *A61B 2018/00226* (2013.01); *A61B 2018/00559* (2013.01); *A61B 2018/00982* (2013.01); *A61B 2018/1861* (2013.01)

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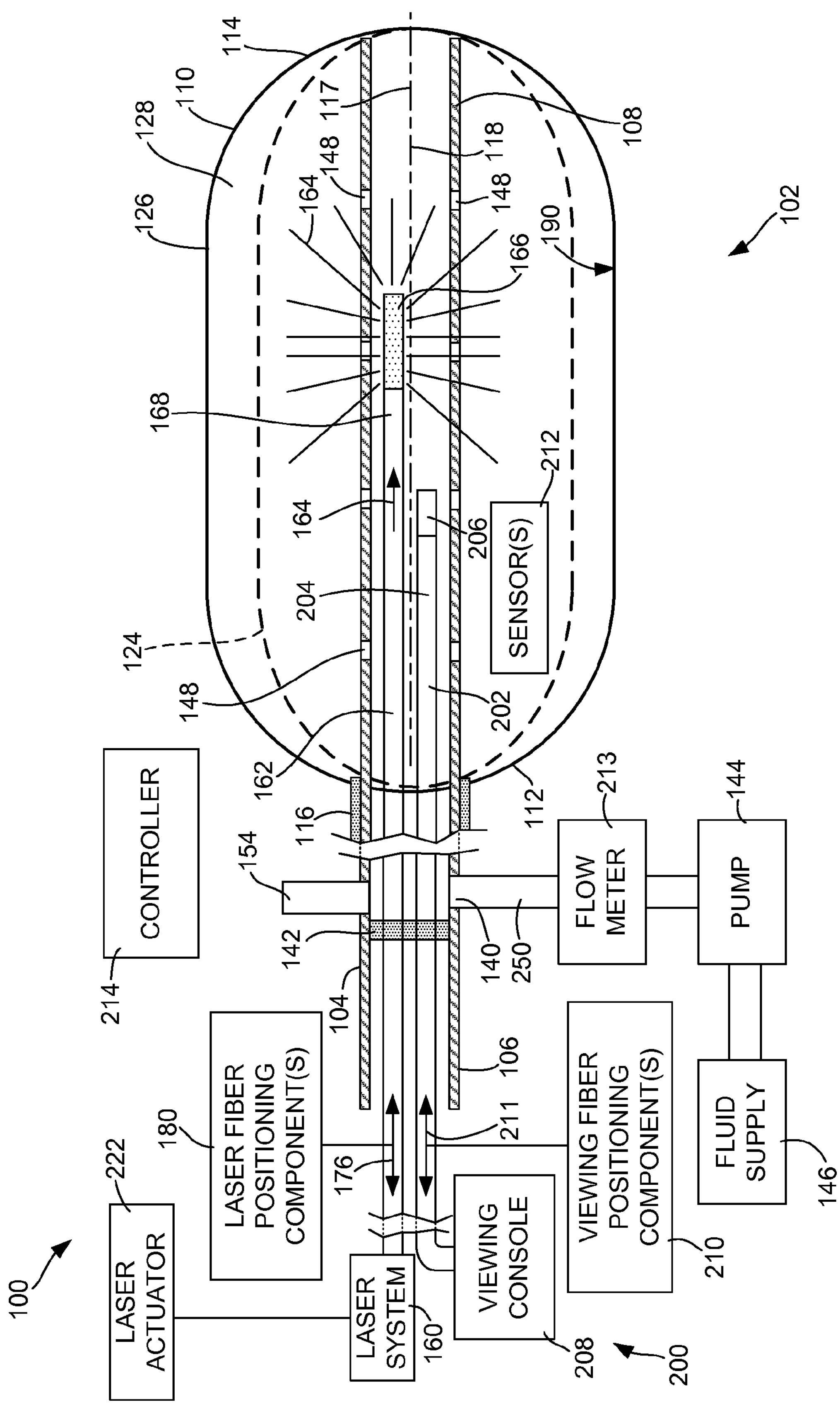
CONTROLLER
SENSOR(S)
FLOW METER
PUMP
FLUID SUPPLY
LASER FIBER POSITIONING COMPONENT(S)
VIEWING FIBER POSITIONING COMPONENT(S)
LASER ACTUATOR
LASER SYSTEM
VIEWING CONSOLE

FIG. 1

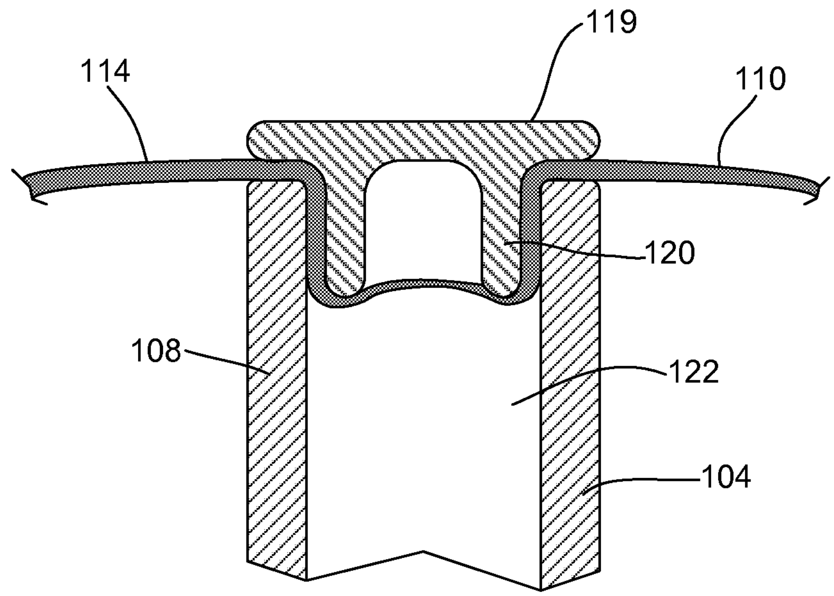

FIG. 2

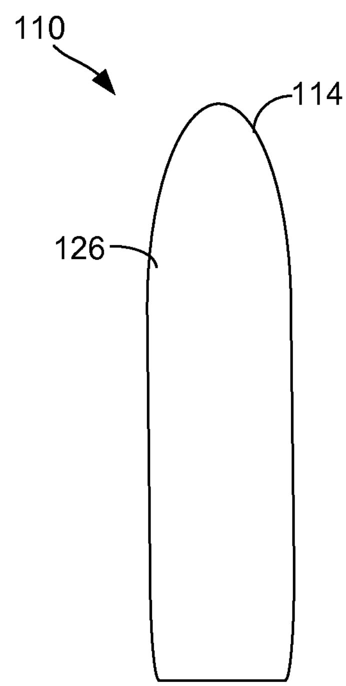

FIG. 3

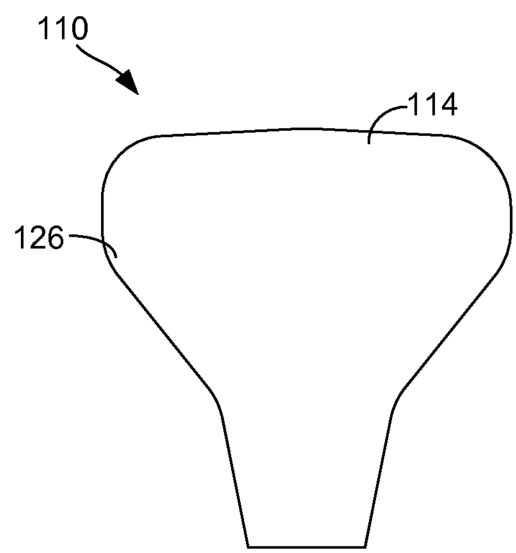

FIG. 4

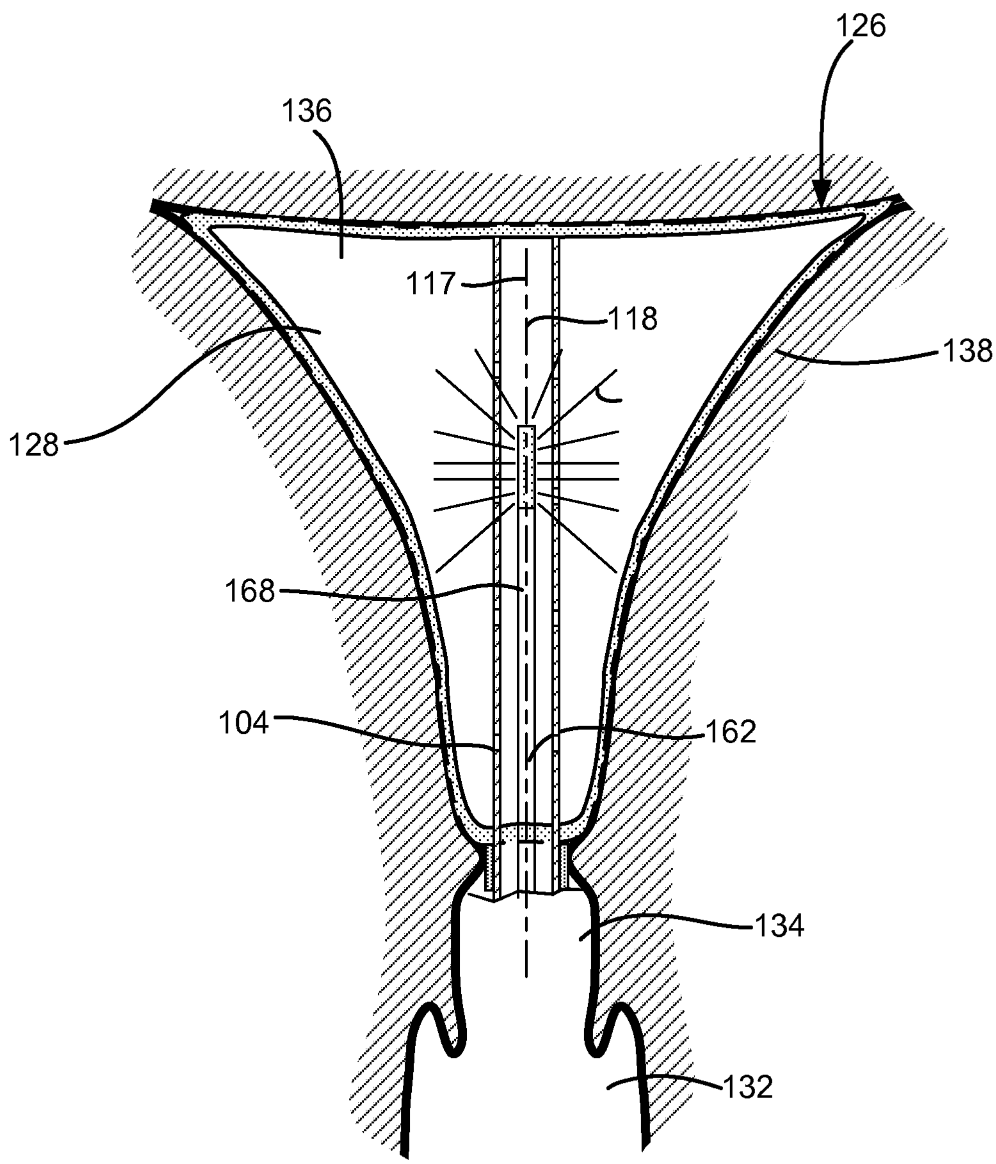

FIG. 5

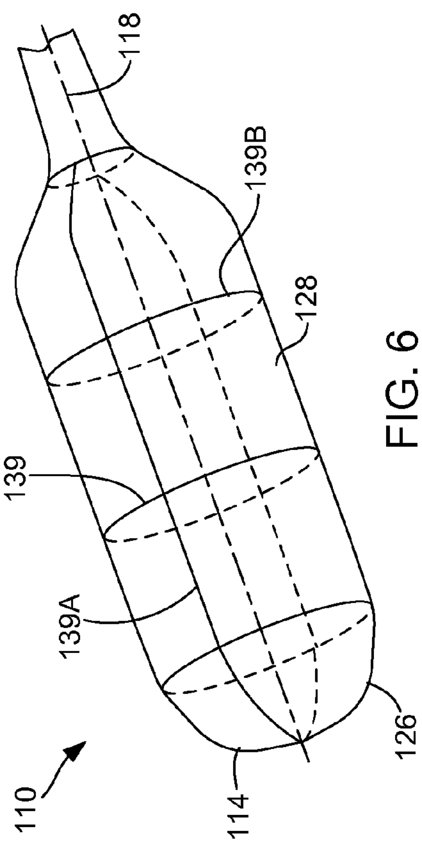

FIG. 6

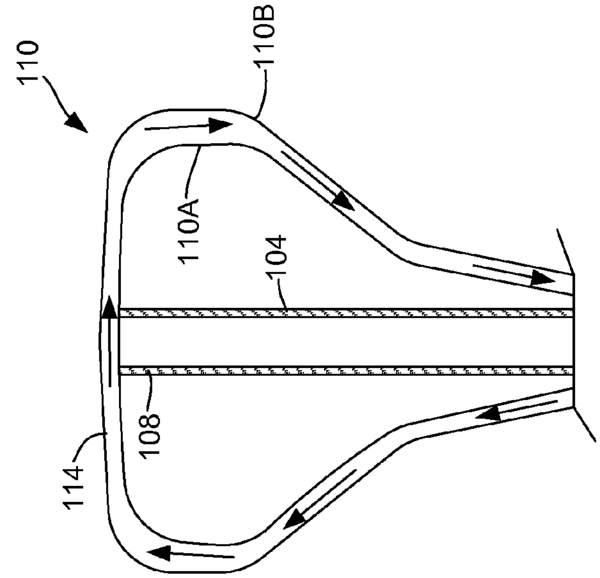

FIG. 8

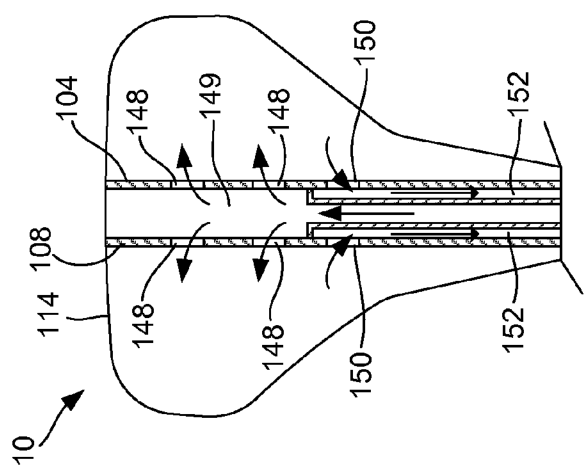

FIG. 7

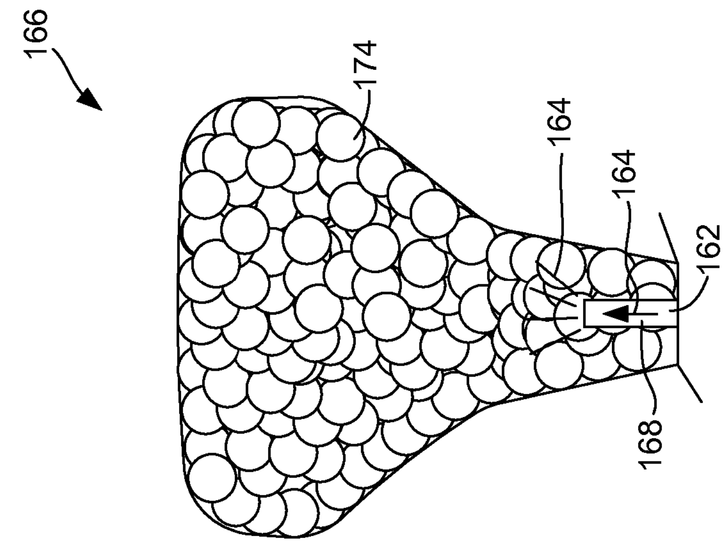

FIG. 10

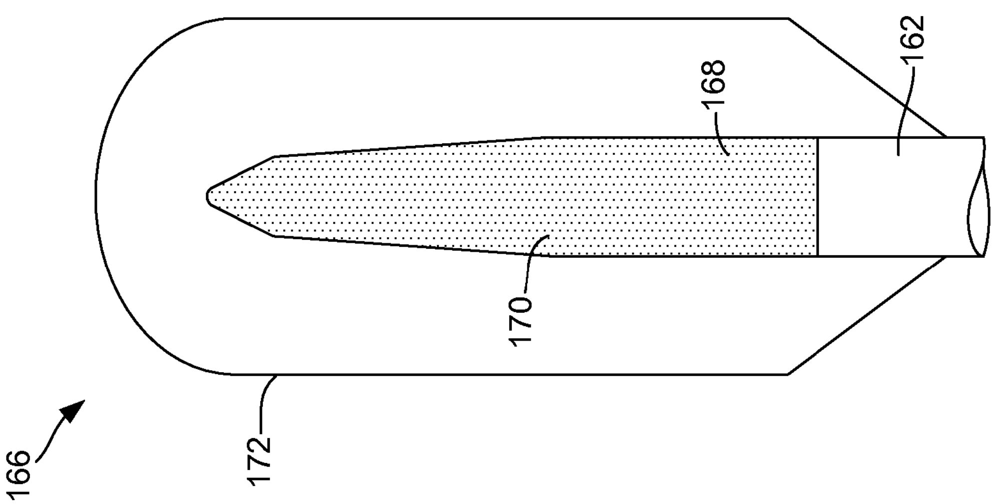

FIG. 9

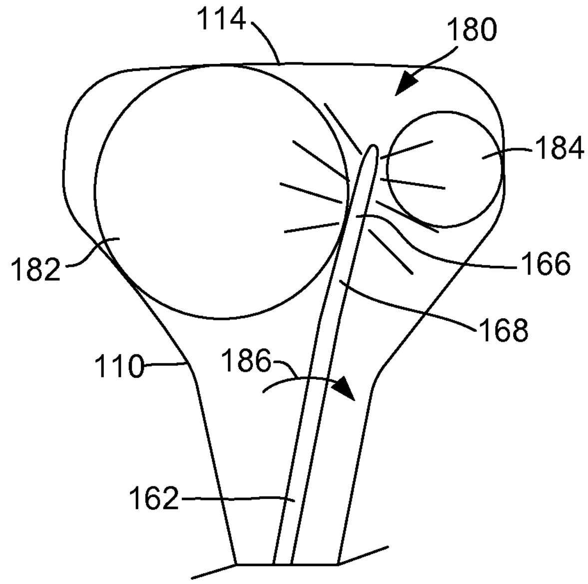
114
180
184
182
166
168
110
186
162

FIG. 11

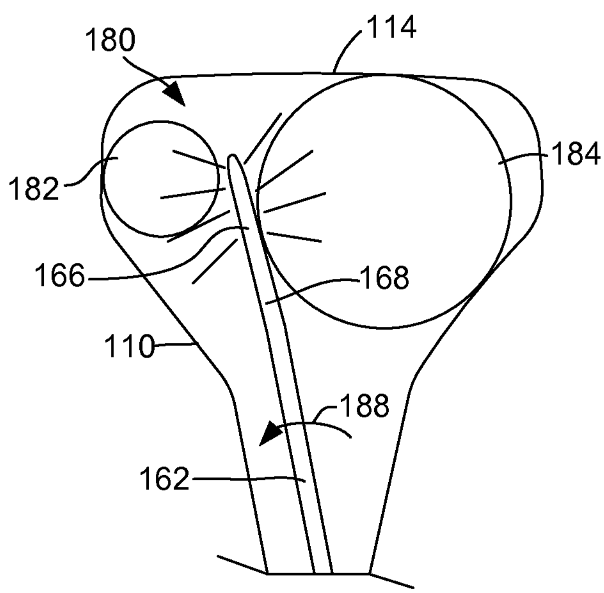
180
114
182
184
166
168
110
188
162

FIG. 12

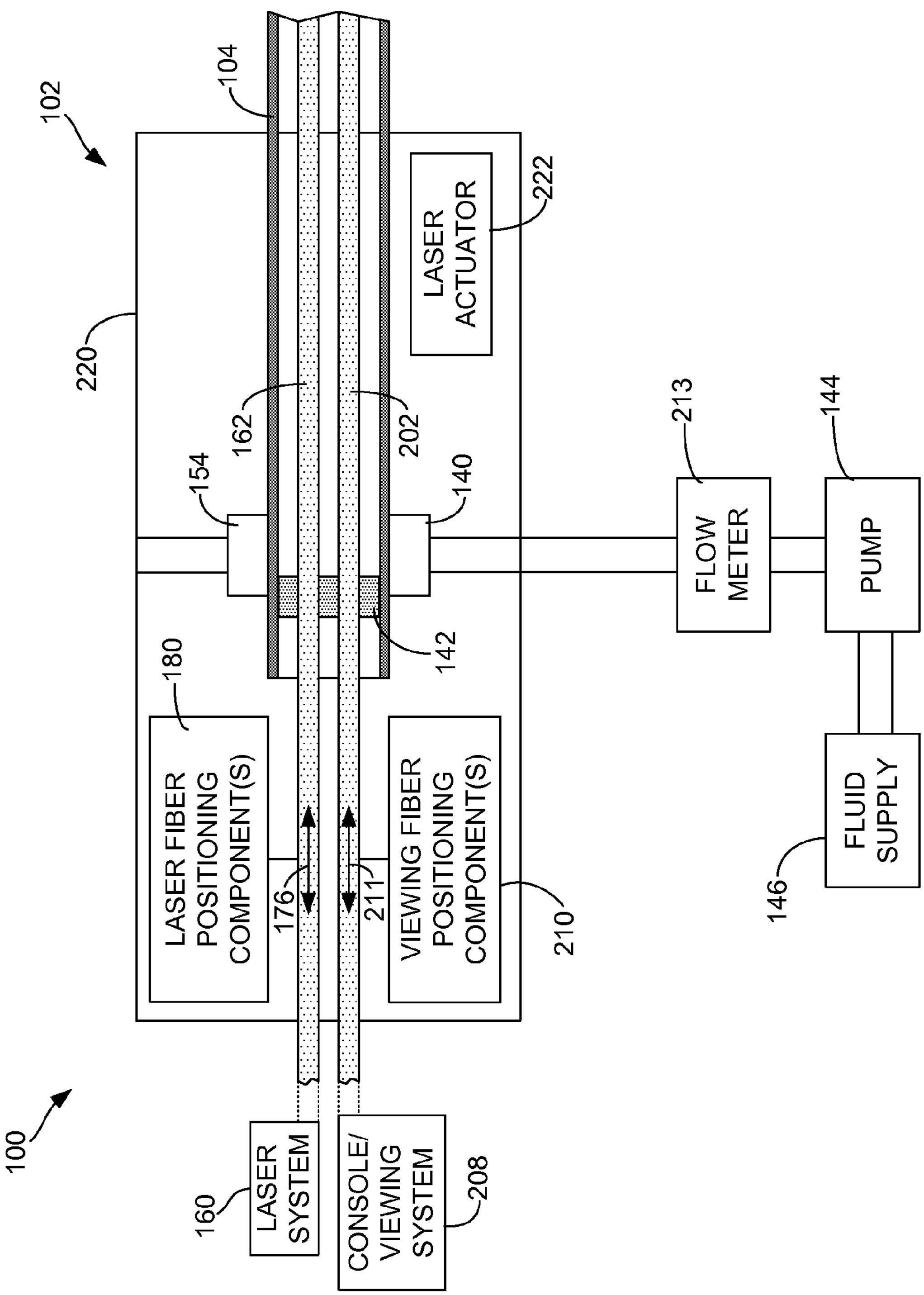
102
104
222
LASER ACTUATOR
220
162
202
154
140
213
FLOW METER
144
PUMP
142
180
LASER FIBER POSITIONING COMPONENT(S)
VIEWING FIBER POSITIONING COMPONENT(S)
176
211
210
FLUID SUPPLY
146
100
160
LASER SYSTEM
CONSOLE/ VIEWING SYSTEM
208

FIG. 13

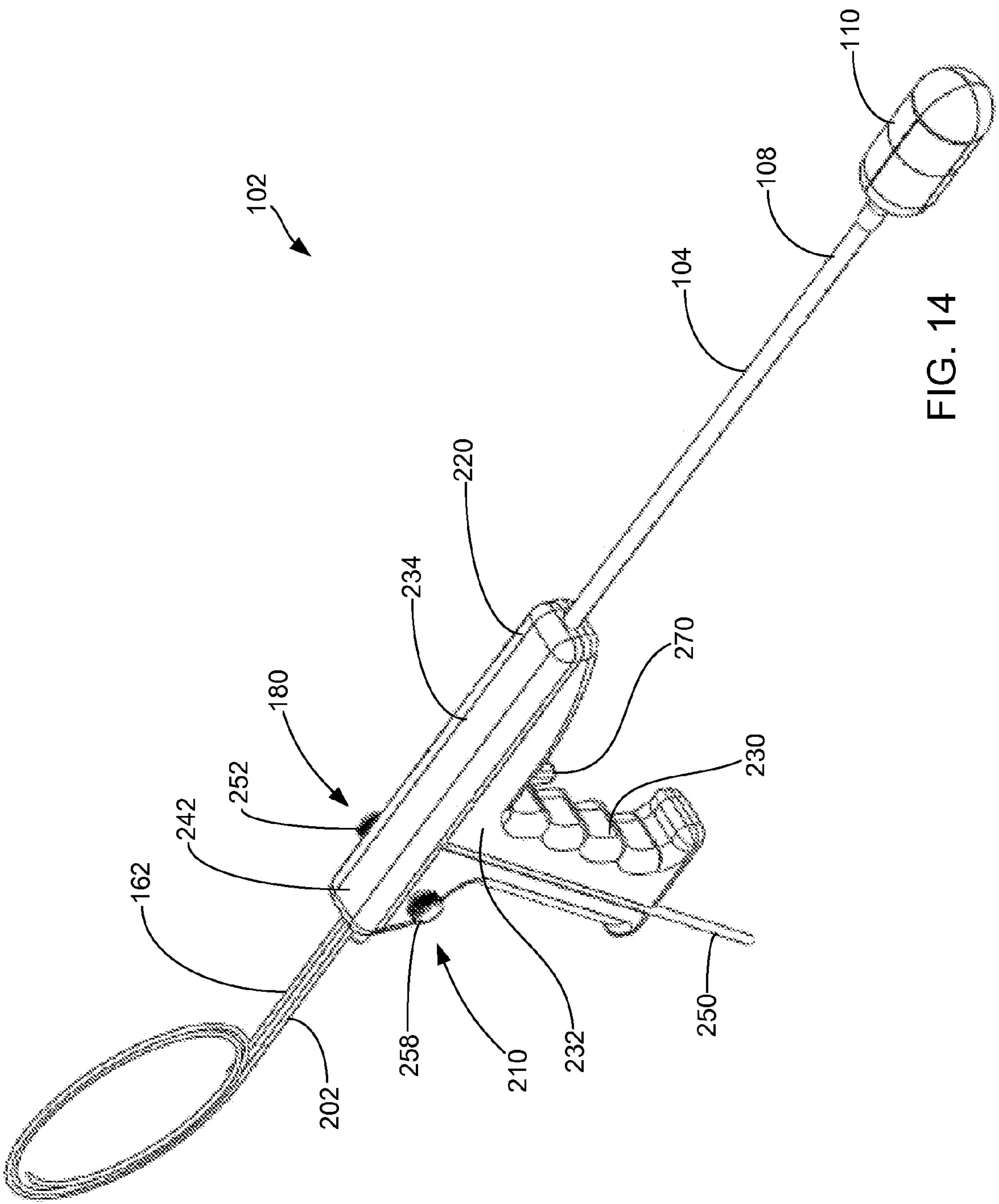
102
110
108
104
220
234
270
180
230
252
242
162
258
210
232
250
202

FIG. 14

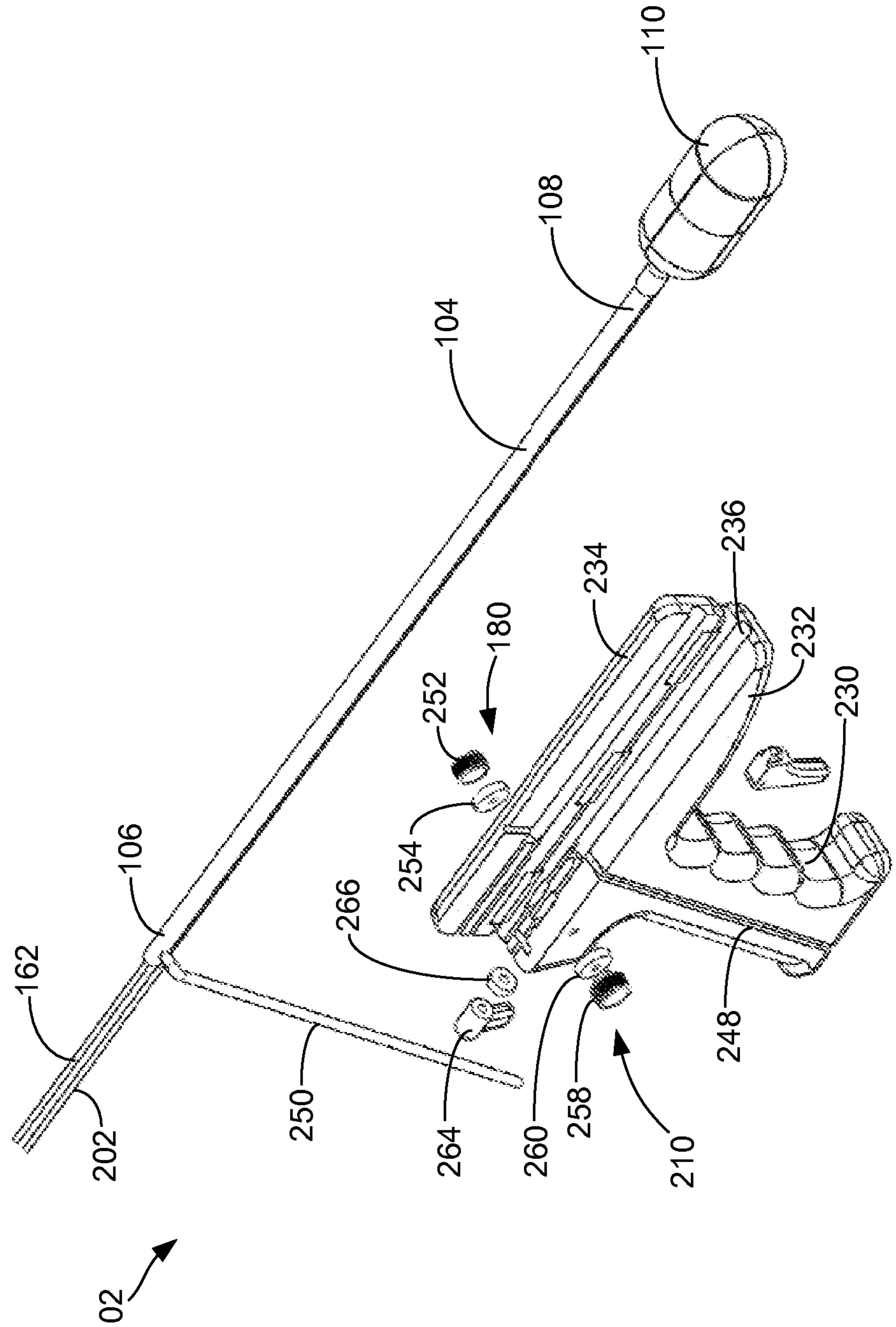
110
108
104
106
162
202
250
264
266
260
258
210
102
180
252
254
234
236
232
230
248

FIG. 15

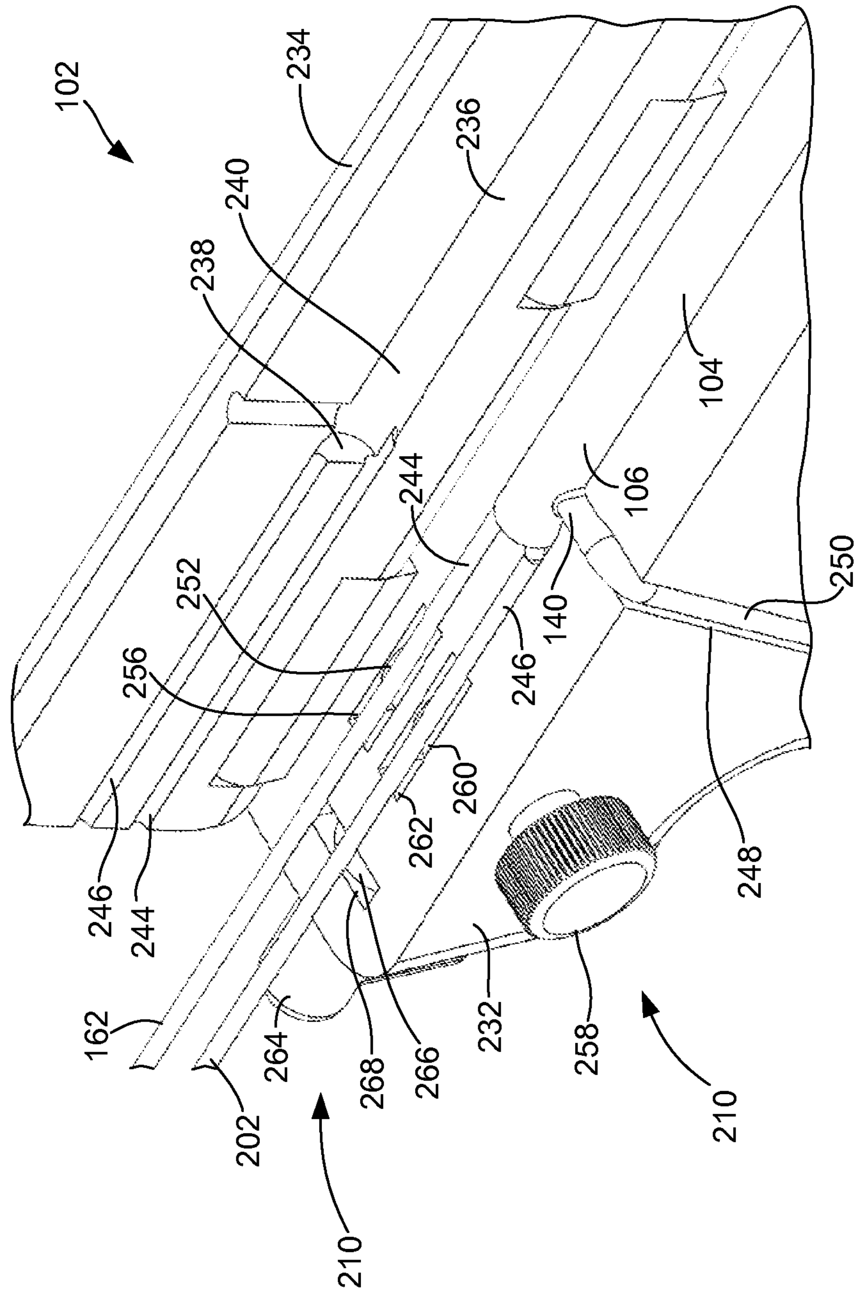
102
234
236
240
238
104
244
106
252
256
140
250
246
260
262
246
244
248
162
264
268
266
232
258
202
210
210
210

FIG. 16

LASER TISSUE ABLATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

This Application is a continuation of U.S. application Ser. No. 13/152,825, filed Jun. 3, 2011, which claims the benefit of U.S. provisional application Ser. No. 61/351,127 filed Jun. 3, 2010. The content of each of the above-identified applications are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

Pelvic conditions include diseases of the uterus, such as uterine fibroids and menorrhagia. Uterine fibroids are non-cancerous tumors of the uterus that typically appear on the endometrium layer (i.e., uterine wall) of the uterus. Menorrhagia is a medical condition involving excessive and difficult to control bleeding of the endometrial layer of the uterus. These conditions have been treated through hysterectomy. However, alternative, less radical approaches are also being used.

One alternative to a hysterectomy is endometrial ablation, which induces necrosis of the endometrial layer and a portion of the myometrial layer. These treatments can include freezing and heating the endometrial layer, or cauterizing the endometrial layer using a laser.

SUMMARY

Some embodiments of the invention are directed to a laser ablation system. In one embodiment, the laser ablation system comprises a shaft, a balloon, a laser fiber and a viewing fiber. The shaft has a proximal end and a distal end. The balloon is attached to the distal end of the shaft, a portion of which is within the balloon. The laser fiber has a distal end comprising a light dispenser that is configured to deliver laser light through the balloon. The viewing fiber is configured to image an interior balloon.

In accordance with another embodiment, the laser ablation system comprises a shaft, a balloon and a laser fiber. The shaft has a proximal end and a distal end. The balloon is attached to the distal end of the shaft, which is within the balloon. The balloon includes an inflated state, in which the balloon is shaped to conform to a cavity of a patient. The laser fiber has a distal end comprising light dispenser that is configured to deliver laser light through the balloon.

Additional embodiments are directed to a method a using the laser ablation system. In one embodiment, a laser ablation system is provided that comprises a shaft, a balloon and a laser fiber. The shaft has a proximal end and a distal end. The balloon is attached to the distal end of the shaft, which is within the balloon. The balloon includes an inflated state, in which the balloon is shaped to conform to a uterine cavity of a patient. The laser fiber has a distal end comprising a light dispenser that is configured to deliver laser light through the balloon. Also in the method, the distal end of the shaft is fed into the uterus of a patient with the balloon in a deflated state. The balloon is inflated with a gas or fluid to the inflated state, in which the balloon substantially conforms to the uterine cavity of the patient and engages the uterine walls. Laser light is then transmitted through the laser fiber and, the light dispenser and the balloon. The tissue of the uterine walls is ablated responsive to the transmission of the laser light.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a simplified diagram of a laser tissue ablation system formed in accordance with embodiments of the invention.

FIG. **2** is a cross-sectional view illustrating the attachment of a distal end of a shaft to a balloon, in accordance with an exemplary embodiment.

FIGS. **3** and **4** are simplified diagrams of inflated balloons in accordance with embodiments of the invention.

FIG. **5** is a cross-sectional view depicting pelvic anatomy of a female patient and a distal end of the applicator formed in accordance with embodiments of the invention.

FIG. **6** is an isometric view of a balloon in accordance with embodiments of the invention.

FIGS. **7** and **8** are side cross-sectional views of a distal end of an applicator illustrating fluid or gas flow in accordance with embodiments of the invention.

FIGS. **9** and **10** are side views of light dispensers in accordance with embodiments of the invention.

FIGS. **11** and **12** are side views of the distal end of the applicator illustrating laser fiber positioning components in accordance with embodiments of the invention.

FIG. **13** is a simplified diagram of the applicator including a handheld unit in accordance with embodiments of the invention.

FIGS. **14-16** respectively show isometric assembled, isometric exploded and magnified isometric views of the applicator with a handheld unit formed in accordance with exemplary embodiments of the invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Embodiments of the present invention are directed to a laser tissue ablation system designed to perform tissue ablation and/or other laser treatments on a patient. While particular embodiments of the invention will be described as useful in treating menorrhagia through endometrial ablation of the uterine wall of a patient, those skilled in the art understand that the system of a present invention may be adapted to perform ablation treatments of other tissue of a patient, such as that of the anal cavity, the bladder, the vagina, the esophagus, the trachea, the urethra, the ureter, the prostate gland, the kidney, intestinal growths or abnormal tissues of the intestine (e.g., hemorrhoids, polyps, etc.) and cancerous tissues.

FIG. **1** is a simplified diagram of a laser tissue ablation system **100** formed in accordance with embodiments of the invention. One embodiment of the system **100** includes an applicator **102** that is formed in accordance with the embodiments described below.

One embodiment of the applicator **102** comprises a shaft **104** having a proximal end **106** and a distal end **108**. One embodiment of the shaft **104** is formed of a rigid and substantially transparent material, such as, for example, acrylic, PET, silicone, polyurethane, polycarbonate, glass or other suitable material. In one embodiment, the applicator **102** includes a balloon **110** that is attached to the shaft **104** proximate the distal end **108**. In one embodiment, the balloon **110** comprises a proximal end **112** and a distal end **114**. In one embodiment, the proximal end **112** is attached to the shaft **104** by a sleeve **116** that is formed, for example out of Teflon®, which seals an opening of the balloon **110** to the shaft **104**.

In one embodiment, the distal end **108** of the shaft **104** is attached to the distal end **114** of the balloon **110**. In one embodiment, the shaft **104** has a longitudinal axis **117**. In one embodiment, the distal end **108** of the shaft **104** is secured to the distal end **114** of the balloon **110** along longitudinal axis **117**. In one embodiment, the longitudinal axis **117** is aligned with a central axis **118** of the balloon **110**. In one embodiment, the balloon is symmetric about the longitudinal or central axis **117** when inflated.

The attachment of the balloon **110** to the shaft **104** can be accomplished in many different ways. FIG. **2** is a cross-sectional view illustrating an exemplary means of attaching the shaft **104** to the balloon **110** using a cap **119**. The cap **119** comprises a cylindrical portion **120** that is received within a bore **122** of the shaft **104**. The distal end **114** of the balloon **110** is captured between the surfaces of the cylindrical portion **120** of the cap **119** and the shaft **104**. In one embodiment, frictional resistance prevents the cap **119** from becoming dislodged from the bore **122** of the shaft **104**. A biocompatible adhesive may also be used to secure the cap **119** to the distal end **108** of the shaft **104**. Other techniques may also be used to secure the balloon **110** to the distal end **108** of the shaft **104**.

The balloon **110** has deflated and inflated states. The deflated state **124** of the balloon **110** is preferably sufficiently compact to allow the distal end **108** of the shaft **104** and the attached balloon **110** to be inserted into the desired cavity of the patient, such as the uterus or vagina, to locate the balloon **110** proximate the tissue targeted for treatment. In one embodiment, the deflated state of the balloon **110** is approximately 4-6 mm or less in diameter measured radially from the central axis **118** of the balloon **110**. When in the inflated state, the balloon **110** substantially conforms to the cavity in which it is placed.

In one embodiment, the balloon **110** is be formed of a suitable biocompatible material. In one embodiment, the balloon **110** is formed of a distensible material, such as silicone, PET, polyurethane, rubber or other suitable material. The distensible material can stretch responsive to inflating the balloon **110** from a deflated state **124** (illustrated in phantom in FIG. **1**) to an inflated state **126** (solid line), as shown in FIG. **1**, due to an increase in the pressure of the interior **128** of the balloon **110**. The distensible material allows the balloon **110** to further conform to the cavity of the patient in which it is placed in response to pressure exerted on the balloon **110** from the walls of the cavity.

In accordance with another embodiment, the balloon **110** is formed of minimally distensible material, such as polyurethane, or other suitable material.

In one embodiment, the balloon **110** includes an Inhibizone coating, such as that described in U.S. Pat. No. 5,756,145, which is incorporated herein by reference in its entirety.

FIGS. **3** and **4** are simplified diagrams of the balloon **110** in the inflated state **126**, in accordance with embodiments of the invention. In one embodiment, the inflated state **126** of the balloon **110** has a cylindrical shape with a rounded distal end **114**, as illustrated in FIGS. **1** and **3**.

In accordance with another embodiment, the inflated state **126** of the balloon **110** has a predefined non-cylindrical or spherical shape when viewed in a plane aligned with the central axis of the balloon **117**. Rather, the inflated state **126** of the balloon has a shape that conforms to the interior cavity of the patient where the tissue targeted for ablation is located. One exemplary embodiment is illustrated in the simplified side view of FIG. **4**, in which the inflated state **126** of the balloon **110** is shaped to conform to the uterus of a patient. The balloon **110** can take on other cavity-conforming shapes, such as the vagina, the anal cavity, esophagus, trachea, bladder and any other cavity within the body.

When the balloon **110** is formed of substantially non-distensible material, the predefined inflated shape **126** of the balloon **110** will drive the tissue of the cavity into conformity with the balloon **110**. When the balloon **110** is formed distensible material, the inflated state **126** of the balloon will generally conform to the cavity of the patient. As a result, the balloon **110** may only minimally deflect the walls of the cavity when the balloon is inflated. Further, the balloon **110** will also deform in response to engagement with the walls of the cavity.

In one embodiment, the pre-defined shape of the inflated state **126** of the balloon prevents the balloon from applying significant pressures to the walls of the cavity of the patient. In one embodiment, the balloon **110** applies less than 10 psi to the walls of the cavity of the patient in which it is inflated. Thus, the balloon **110** having a pre-defined inflated shape can significantly reduce the pressure on the walls of the cavity of the patient in which the balloon **110** is inflated. This can reduce patient intraoperative and post operative pain.

FIG. **5** is a cross-sectional view of a female patient depicting the vagina **132**, the cervix **134** and the uterus **136**. The distal end **108** of the shaft **104** and a balloon **110** are inserted through the cervix **134** and into the uterus **136** when the balloon **110** is in the deflated state **124**. The balloon **110** is then expanded to the inflated state **126** (shown), in which the balloon **110** substantially conforms to the shape of the uterine wall **138**. The balloon **110** preferably engages the uterine wall **138** while applying minimal pressure. In one embodiment, the balloon **110** applies less than 10 psi to the uterine wall **138** when in the inflated state **126**.

In one embodiment, the balloon **110** includes markings **139**, as shown in FIG. **6**. The markings **139** can be viewed from within the interior **128** to determine whether the balloon **110** is properly inflated and/or positioned within the cavity of the patient. In one embodiment, the markings **139** comprise one or more visible lines extending longitudinally (i.e., lines **139**A), and/or circumferentially (i.e., lines **139**B) around the balloon **110**. In one embodiment, the markings **139** comprise a grid pattern.

In one embodiment, the balloon **110** seals the distal end **108** of the shaft **104**. A seal **142**, such as an o-ring, or other suitable seal, seals the proximal end **106** of the shaft **104**. In one embodiment, the balloon **110** is inflated using a simple saline solution.

In one embodiment, the balloon **110** may be inflated with fluid or gas. In one embodiment, the shaft **104** includes a port **140**, as shown in FIG. **1**, through which the fluid or gas may be received. In one embodiment, the system **100** comprises a pump **144** that drives a fluid or gas from a supply **146** through the port **140** and into the interior **128** of the balloon **110** to drive the balloon **110** to its inflated state **126**. The pump **144** can take on many different forms. In one embodiment, the supply **146** is in the form of a pressurized gas, in which case, the pump **144** may represent a valve that controls the flow of the gas from the supply **146**. In accordance with another embodiment, the pump **144** drives a fluid from the supply **146** through the port **140** and into the interior **128** of the balloon **110** to inflate the balloon **110**. Embodiments of the pump **144** include a syringe, a diaphragm pump, gear pump, or other suitable pump.

In one embodiment, gas or fluid enters the shaft **104** through the port **140**, shown in FIG. **1**. In one embodiment, the shaft **104** includes a fluid path **149** that fluidically couples the port **140** to openings **148** in the shaft **104** to the interior **128** of the balloon **110**, as shown in FIG. **7**. The gas or fluid entering the port **140** flows through the fluid path **149**, through the openings **148** and into the interior **128** of the balloon **110** as shown in FIGS. **1** and **7**. In accordance with one embodiment, the fluid or gas within the interior cavity **128** of the balloon **110** may be discharged back through the openings **148** of the shaft **104** and out the port **140**. Alternatively, as shown in FIG. **7**, the fluid or gas within the interior cavity **128** of the balloon **110** may be discharged through one or more openings **150** to a fluid path **152** that is connected to a dedicated drain port **154** (FIG. **1**).

In accordance with one embodiment, the balloon **110** comprises an interior balloon **110**A and an exterior balloon **110**B, as shown in the simplified side-cross sectional view of FIG. **8**. In accordance with one embodiment, either the interior balloon **110**A or the exterior balloon **110**B is formed of a non-distensible material, while the other balloon **110**A or **110**B is formed of a distensible material. In one embodiment, the interior balloon **110**A is formed of a substantially non-distensible or minimally distensible material and has a predefined shaped in accordance with embodiments described above. In accordance with one embodiment, a biocompatible lubricant is located between the interior balloon **110**A and the exterior balloon **110**B.

In accordance with one embodiment, the fluid or gas driven through the port **140** is fed between the interior balloon **110**A and the exterior balloon **110**B, as represented by the arrows in FIG. **8**. In one embodiment, the fluid is discharged through the fluid path **152** and out the drain port **154**. The flow of fluid between the balloons **110**A and **110**B can be used to control the temperature of the tissue that is in contact with the balloon **110**B.

One embodiment of the system **100** includes a conventional laser source **160** that can be attached to a waveguide **162**, such as an optical fiber (hereinafter "laser fiber"), that can be received within the shaft **104**. The laser source **160** can be a conventional laser generating system. In accordance with one embodiment, the laser source **160** is configured to generate laser light or a laser **164** having a desired wavelength for performing surgical procedures, such as tissue ablation.

In one embodiment, the laser source **160** is configured to produce an Nd:YAG laser operating at approximately 532 nanometers or 1064 nanometer wavelengths. The laser source **160** may be a solid state laser based on a potassium-titanyl-phosphate (KTP) crystal, a lithium triborate (LBO) laser, a beta barium borate (BBO), a holmium laser and a thulium laser, or other type of laser source used to perform tissue ablation or other laser treatment. Exemplary laser sources **160** are described in U.S. Pat. No. 6,986,764 (Davenport), which is incorporated herein by reference in its entirety.

The laser **164** generated by the laser source **160** travels through the laser fiber **162** and is discharged through a light dispenser **166** at a distal end **168**. In one embodiment, the dispensed laser light **164** is transmitted through the shaft **104** and the balloon **110** and onto the targeted tissue of the patient, such as the uterine wall **138** shown in FIG. **5**.

The light dispenser **166** is configured to discharge the laser light **164** in a desired manner, such as along the axial and/or radial directions of the laser fiber **162**, to one side of the laser fiber **162**, in a diffuse pattern around the dispenser **166**, and/or other desired manner. Exemplary light dispensers **166**, such as side-fire optical caps, are disclosed in U.S. Pat. No. 5,428,699 (Pon), U.S. Pat. No. 5,269,777 (Doiron et al), U.S. Pat. No. 5,530,780 (Ohsawa), and U.S. Pat. No. 5,807,390 (Fuller et al).

In one embodiment, the light dispenser **166** comprises an etched section **170** of the laser fiber **162**, as shown in FIG. **9**, to dispense the laser light **164** in a diffuse pattern. In one embodiment, portions of the etched section **170** are tapered to direct the diffused laser light in a desired manner, such as axially. The etching can be made using an appropriate laser, such as a CO_2 laser, to roughen the exterior surface of the laser fiber **162**. In one embodiment, a cap **172** encloses the dispenser **166**, as shown in FIG. **9**.

If the laser light **164** is output from the dispenser **166** in an even dispersion pattern, the targeted tissue located farther away will receive less laser light energy than the targeted tissue located closer to the dispenser **166**. In one embodiment, the etching pattern of the section **170** is customized to include portions that transmit more light energy than other portions to customize the laser energy dispersion pattern output from the dispenser **166**. That is, the etched section **170** may comprise different patterns in different portions of the section **170** to provide different levels of laser light transmission through the different portions of the section **170**. This allows the targeted tissue to receive similar intensity levels of the dispensed laser light **164** even though the targeted tissue is not located a uniform distance from the dispenser **166**.

In accordance with one embodiment, light transmission through the balloon **110** is non-uniform. In one embodiment, light transmission through the balloon varies along the central axis **118** of the balloon **110**. That is, portions of the balloon **110** at different locations along the axis **118** (e.g., portions in a plane that is perpendicular to the axis **118**) have a degree of laser transparency that is different from other portions of the balloon along the axis **118**. This allows for the control of the transmission of the laser light **164** through the balloon **110** and, therefore, the amount of laser energy that is delivered to the targeted tissue.

In one embodiment, the material forming the balloon provides a predefined pattern of laser transparency variation along the axis **118**, such as, for example, by varying a thickness of the balloon **110**. In one embodiment, printing or a coating of material on of the balloon **110**, such as on the interior wall **190** (FIG. **1**), defines the desired pattern of laser transparency though the balloon **110**. In one embodiment, the printing or coating defines the pattern of laser transparency by applying the printing or coating to select portions of the balloon **110**, applying the printing or coating in a varying pattern on the balloon **110**, and/or applying the printing or coating in a varying thickness on the balloon **110**. Embodiments of the coating may comprise titanium dioxide (TiO_2), Tampapur Ink, and/or parylene. In one embodiment, the coated or printed material is reflective.

FIG. **10** illustrates a simplified diagram of a light dispenser **166** in accordance with another embodiment of the invention. In accordance with this embodiment, the light dispenser **166** comprises a plurality of glass beads **174** within the balloon **110**. The laser light is discharged through the distal end **168** of the laser fiber **162** and interacts with the glass beads **174** to disperse the laser light **164** around the surface of the balloon **110**.

In one embodiment, the distal end **108** of the shaft **104** is configured to transmit the laser light **164** discharged through the dispenser **166** of the laser fiber **162** at varying degrees of efficiency. That is, sections of the shaft **104** are configured to be more transparent to the laser light **164** than other sections of the shaft **104**. This pattern of laser transparency of the shaft may be formed in various ways. In one embodiment, the interior or exterior wall of the shaft **104** is coated as described above with regard to the balloon **110**. Alternatively, the pattern may be formed on the shaft **104** by etching the pattern on the shaft **104**, applying a particulate to the shaft **104** that blocks the laser light **164**, tinting the shaft **104**, or other suitable technique for creating the desired pattern of laser transparency through the shaft **104**. As discussed above with regard to the dispenser **166** illustrated in FIG. **9**, the control of the transmission of the laser light **164** through the shaft **104** provides control over the amount of laser energy that is delivered to the targeted tissue.

One embodiment of the system **100** includes one or more laser fiber positioning components **180** represented schematically in FIG. **1**. In one embodiment, the positioning components **180** are configured to move the laser fiber **162** axially along the longitudinal axis of the laser fiber, as indicated by arrow **176** in FIG. **1**, relative to the shaft **104** and/or the balloon **110**. This axial movement of the distal end **168** laser fiber **162** causes the laser fiber **162** to generally move along the longitudinal axis **117** of the shaft **104** and along the central axis **118** of the balloon **110** relative to the balloon **110** and the shaft **104**. In accordance with one embodiment, the distal end **168** of the laser fiber **162** may be moved axially by the one or more components **180** to withdraw the distal end **168** and the dispenser **166** of the laser fiber **162** from within the interior **128** of the balloon **110**. The components **180** may also move the distal end **168** and the dispenser **166** of the laser fiber **162** into the interior **128** of the balloon **110**. Thus, the dispenser **166** of the laser fiber **162** may be positioned in the desired location relative to the balloon **110** and the shaft **104** using the one or more laser fiber positioning components **180**.

In accordance with another embodiment, the laser fiber positioning components **180** are configured to rotate the laser fiber **162** about its longitudinal axis and, thus, rotate (i.e., move angularly) the dispenser **166** about the longitudinal axis. This may be useful when the dispenser **166** is configured to output the laser light **164** radially out a side of the dispenser **166** over a range of less than 360 degrees. With such a configuration, the dispenser **166** can be made to output the laser light **164** to the tissue surrounding the dispenser **166** by rotating the dispenser 360 degrees using the positioning components **180**.

In accordance with one embodiment, the one or more positioning components **180** are configured to move the distal end **168** of the laser fiber **162** in an arc relative to the balloon **110**. FIGS. **11** and **12** illustrate exemplary components **180** for moving the distal end of the laser fiber **162** in an arc. In one embodiment, the components **180** comprise at least two balloons **182** and **184** that may be inflated and deflated through the pumping of a gas or fluid through suitable conduit (not shown) coupled to the balloons **182** and **184**. In one embodiment, the distal end **168** of the laser fiber **162** is not covered by the shaft **104**. Movement of the distal end **168** of the laser fiber **162** along an arc in the direction indicated by arrow **186** is accomplished by deflating the balloon **184** and inflating the balloon **182**, as shown in FIG. **11**. Likewise, the distal end **168** of the laser fiber **162** may be moved in an arc in the direction indicated by arrow **188** by deflating the balloon **182** and inflating the balloon **184**, as shown in FIG. **12**. Additional balloons may be used in a similar manner to displace the distal end **168** of the laser fiber **162** along an arc in the desired direction.

One embodiment of the system **100** includes a viewing system **200** that is configured to provide the physician with a view from the interior **128** of the balloon **110**. One embodiment of the viewing system **200** comprises a viewing fiber **202** that is received within the shaft **104**, as shown in FIG. **1**. In one embodiment, the distal end **204** comprises an imaging component **206**, such as a charge coupled device (CCD) that is configured to image the interior **128** of the balloon **110** through the shaft **104**. The imaging component **206** may be a conventional device that includes the necessary electronics to deliver the image data down the viewing fiber **202** to a suitable viewing console **208** through one or more wires (not shown). A capsule or other protective means can protect the imaging component **206** from the environment within the interior **128** of the balloon **110**.

In one embodiment, the viewing system **200** includes one or more viewing fiber positioning components **210** that are configured to adjust the position and/or orientation of the imagining component **206** to image the desired portion of the balloon **110** or the targeted tissue of the patient. In one embodiment, the positioning components **210** are configured to move the viewing fiber **202** axially along the longitudinal axis of the viewing fiber, as indicated by arrow **211** in FIG. **1**, relative to the shaft **104** and/or the balloon **110**. Accordingly, the distal end **204** of the viewing fiber **202** may be moved axially by the one or more components **210** to withdraw the imaging component **206** from within the interior **128** of the balloon **110**. The imagining component **206** can be moved from this withdrawn position into the interior **128** of the balloon **110** and positioned in a desired location relative to the balloon **110** and the shaft **104**. In accordance with another embodiment, the viewing fiber positioning components **210** are configured to rotate the viewing fiber **202** about its longitudinal axis and, thus, rotate the imagining component **206** about the longitudinal axis of the viewing fiber **202**. This allows the imaging component **206** to image a full 360° around the longitudinal axis of the viewing fiber **202**.

Exemplary positioning components for the laser fiber **162** and the components **210** for the viewing fiber **202** include components that facilitate the hand feeding of the fibers **162** and **202**, and components that drive the feeding of the laser fiber **162** and the viewing fiber **202**, such as rollers that are rotated by hand or driven by a motor, or other suitable mechanism for feeding the laser fiber **162** and the viewing fiber **202** in their axial directions. In one embodiment, the components **180** and **210** are configured to rotate the laser fiber **162** and the viewing fiber **202**, respectively, and include components that facilitate the rotation of the fibers by hand, mechanisms that are driven by hand or by a motor that engage the fibers and rotate the fibers about their longitudinal axis, or other components that can be used to rotate the fibers.

Another embodiment of the system **100** includes one or more sensors **212** (FIG. **1**) that are configured to sense a parameter of the system **100** and/or the patient. One embodiment of the sensors includes a temperature sensor, such as a thermal couple, that is configured to sense the temperature of the balloon **110** and/or the tissue of the patient. In accordance with one embodiment, when the balloon **110** comprises and internal balloon **110**A and an external balloon **110**B (FIG. **8**), the temperature sensor is located between the balloons **110**A and **110**B. In accordance with another embodiment, the sensors **212** include a pressure sensor configured to detect a pressure of the interior **128** of the balloon **110**. In one embodiment, the system **100** includes a sensor in the form of a flow meter **213** (FIG. **1**) that is configured to detect the flow rate of fluid driven by the pump **144**. Signals from the one or more sensors **212** are fed via wires or other conventional means to a controller **214** that can use the information received from the sensors **212** to control components of the system **100**, such as the pump **144**.

One embodiment of the applicator **102** comprises a handheld unit **220**, an exemplary embodiment of which is illustrated in FIG. **13**. The handheld unit **220** is generally configured to support components of the applicator **102** described above. In one embodiment, the unit **220** is configured to support the proximal end **106** of the shaft **104**. In one embodiment, the unit **220** is configured to support the laser fiber **162**. In accordance with other embodiments, the handheld unit **220** is configured to support the viewing fiber **202**, the one or more laser fiber positioning components **180** and/or the one or more viewing fiber positioning components **210** described above. In accordance with another embodiment, the handheld unit **220** is configured to receive tubing **250** used to pump fluid or gas through the shaft **104** and into the balloon **110**.

In one embodiment, the handheld unit **220** allows the laser fiber **162** to pass through the body of the unit **220** for attachment to the laser system **160**. Similarly, the handheld unit **220** allows for the viewing fiber **202** to pass through the body of the unit **220** for coupling to the viewing system **208**.

In one embodiment, the handheld unit **220** supports a laser actuator **222** that is configured to trigger the laser system **160** to deliver laser energy down the laser fiber **162** to the distal end **168**. Embodiments of the laser actuator **222** include a button, a finger trigger, or other suitable mechanism. One embodiment of the laser actuator **222** that is not supported by the handheld unit **220** is a foot-activated switch.

FIGS. **14-16** respectively show isometric assembled, isometric exploded and magnified isometric views of the applicator **102** with a handheld unit **220** formed in accordance with exemplary embodiments of the invention. In one embodiment, the handheld unit **220** comprises a pistol grip **230** and a support member **232** that extends transversely to the pistol grip **230**. In one embodiment, the support **232** comprises a hinged cover **234** having a closed position (FIG. **14**) and an opened position (FIG. **15**). A bore **236** is formed in the support **232** and/or the cover **234** and is sized to receive the shaft **104**, as shown in FIG. **16**. In one embodiment, the shaft **104** is securely held within the bore **236** when the cover **234** is in the closed position such that inadvertent movement of the shaft **104** in the longitudinal direction during normal handling of the applicator **102** is prevented. In one embodiment, the support **232** and/or the cover **234** includes a shoulder portion **238** at a proximal end **240** of the bore **236** that prevents the shaft **104** from sliding toward the rear **242** of the support **232** along the longitudinal axis.

In one embodiment, the support **232** and/or the cover **234** comprise a channel **244** that is configured to receive the laser fiber **162**, as best shown in FIG. **16**. The channel **244** extends to the shoulder portion **238** where it receives the laser fiber **162** where it exits the shaft **104**. The channel **244** extends from the shoulder **238** out the rear end of the support **232** where it can be coupled to the laser system **160** in a conventional manner.

Another embodiment of the handheld unit **220** comprises a channel **246** formed in the support **232** and/or the cover **234**, as best shown in FIG. **16**. The channel **246** extends from the shoulder portion **238** out the rear end **242** of the support **232**. The channel **246** is configured to receive the viewing fiber **220** as it exits the proximal end **106** of the shaft **104** and allows the viewing fiber **202** to extend out the rear end **242** of the support member **232** where it can be connected to the viewing system **208**.

In one embodiment, the handheld unit **220** includes a channel **248** configured to receive conduit **250** that is coupled to the fluid input port **140**, as shown in FIG. **16**. In one embodiment, the channel **248** extends through the support **232** and the pistol grip **230**. The exposed end of the conduit **250** may be coupled to the flow meter **213** or pump **144** using conventional means.

As discussed above, one embodiment of the handheld unit **220** includes the one or more laser fiber positioning components **180**. In one embodiment, the laser fiber positioning components **180** comprise a thumb wheel **252** that is coupled to a roller **252** through a gear, axle, or other suitable arrangement, as shown in FIG. **15**. The roller **252** engages the laser fiber **162** through a slot **256** in the support **232**, as shown in FIG. **16**. One embodiment of the roller **252** comprises an exterior surface that comprises rubber or other suitable material that provides sufficient frictional resistance with the exterior of the laser fiber **162** to grip the laser fiber **162** and inhibit sliding contact between the roller **254** and the laser fiber **162**. Rotation of the thumb wheel **252** rotates the roller **254**, which drives the longitudinal movement of the laser fiber **162** in either the forward or rearward direction relative to the handheld unit **220** and the shaft **104**. Thus, one may move the distal end **168** of the laser fiber **162** relative to the balloon **110** to position the distal end **168** as desired.

One embodiment of the one or more viewing fiber positioning components **210** includes a thumb wheel **258** and a roller **260** that operate similarly to the thumb wheel **252** and roller **254** described above to move the viewing fiber **202** in the longitudinal direction relative to the handheld unit **220**, the shaft **104** and the balloon **110**. The thumb wheel **258** is coupled to the roller **260** through a suitable arrangement, such as a gear. The roller **260** is exposed to engage the viewing fiber **202** through a slot **262** in the support **232**. The roller **260** comprises an exterior surface that is formed of a material (e.g., rubber) that generates sufficient frictional resistance with the viewing fiber **202** to inhibit sliding contact between the roller **260** and the viewing fiber **202** as the roller **260** is rotated. Rotation of the thumb wheel **258** causes the roller **260** to rotate, which drives the viewing fiber in the longitudinal direction relative to the handheld unit **220**, the shaft **104** and the balloon **110**. Thus, the longitudinal position of the distal end **204** of the viewing fiber **202** can be positioned as desired relative to the balloon **110** using the thumb wheel **258**.

Another embodiment of the handheld unit **220** comprises one or more viewing fiber positioning components **210** that are configured to rotate the viewing fiber **202** about its longitudinal axis. One embodiment of the components **210** comprise a rotatable member **264**, such as a thumb wheel, and a roller **266**. The rotatable member **264** is coupled to the roller **266** through an axel, gear, or other suitable arrangement, such that rotation of the member **264** causes the roller **266** to rotate. In one embodiment, the axes of rotation of the member **264** and the roller **266** are parallel to the longitudinal axis of the viewing fiber **202** and the channel **246**. The roller **266** engages the viewing fiber **202** through a slot **268**. The exterior surface of the roller **266** is formed of a material (e.g., rubber) that produces sufficient frictional resistance with the viewing fiber **202** to inhibit sliding contact with the viewing fiber **202** as the roller **266** rotates. The rotation of the member **264** causes the roller **266** to rotate, which drives the rotation of the viewing fiber **202** about its longitudinal axis. This allows the distal end **204** of the viewing fiber **202** to be rotated as desired within the balloon **110**. One embodiment of the one or more laser fiber positioning components **180** includes components that are similar to the rotatable member **264** and the roller **266** that can be used to rotate the laser fiber **162** about its longitudinal axis.

In one embodiment, the handheld unit **220** includes the laser actuator **222** in the form of a trigger **270** that is mounted to the support **232**. In one embodiment, actuation of the trigger **270** directs the laser system **160** to transmit laser light through the laser fiber **162** for discharge through the dispenser **166**.

In one embodiment, the shaft **104**, the balloon **110**, the laser fiber **162**, the viewing fiber **202**, the tubing **250**, and/or the port **140** form a disposable group of components. In one embodiment, one or more of these components are provided as a kit in sterilized packaging. In one embodiment, one or more of these components come pre-assembled. For instance, a disposable assembly may comprise the shaft **104**, the balloon **110**, the laser fiber **162** and the tubing, as shown in FIG. **15**, that is ready for installation within the handheld unit **220**. One or more of the other components described above, such as the seal **142**, may also be included the disposable assembly.

Additional embodiments of the invention include methods of ablating tissue of a patient, or performing another laser treatment, using the system **100**. In one embodiment of the method, the system **100** formed in accordance with one or more embodiments described above is provided and the system is prepared for the ablation operation. This may involve the providing of the disposable assembly described above in, for example, sterilized packaging. The disposable assembly is then installed in the handheld unit **202**.

In one embodiment, the laser fiber **162** is connected to the laser system **160**. In one embodiment, the viewing fiber **202** (if present) is connected to the viewing console **208**. In one embodiment, the tubing **250** is fluidically coupled to the pump **144**. In one embodiment, connections are made between the one or more sensors **212** and the controller **214**.

In one embodiment, a coating, such as an adjuvant, is applied to the exterior surface of the balloon **110**, which is placed in contact with the target tissue when the balloon **110** is inflated within the cavity of the patient. The adjuvant is designed to enhance laser tissue ablation by absorbing the wavelength of laser light that will be applied to the tissue. Embodiments of the coating are described in U.S. patent application Ser. No. 12/468,668 filed May 19, 2009 entitled "ADJUVANT ENHANCED ABLATION," which is incorporated herein by reference in its entirety.

In one embodiment, the balloon **110** is placed in the deflated state **124** and the distal end **108** of the shaft **104** is fed into the cavity of the patent, such as the uterus, where the target tissue is located. In one embodiment, the cavity is visually inspected using the viewing fiber **202**.

In one embodiment, the balloon **110** is inflated within the cavity by pumping either fluid or gas through the tubing **250** and the port **140**, such as using the pump **144**. In one embodiment, the inflated state **126** of the balloon engages the interior wall of the cavity, such as illustrated in FIG. **5**.

In one embodiment, the cavity and the inflated balloon **110** are inspected using the viewing fiber **202**. This involves moving the distal end **204** of the viewing fiber **202** axially and/or angularly using the one or more viewing fiber positioning components **210**.

In one embodiment, the markings **139** on the balloon are imaged or viewed using the viewing fiber **202**. The markings indicate whether the balloon **110** is properly inflated and/or positioned within the cavity of the patient. In one embodiment, the balloon **110** is deflated, repositioned and inflated again until the markings **139** indicate that the balloon **110** is fully inflated and/or in the desired position within the cavity.

In one embodiment, the laser fiber **162** is positioned as desired relative to the shaft **104** and the balloon **110** using the one or more laser fiber positioning components **180**. This may involve moving the distal end **168** axially, angularly, or along an arc.

In one embodiment, the laser system **160** is activated to transmit laser light **164** through the laser fiber **162** and out the dispenser **166** to ablate the targeted tissue. In one embodiment, this activation of the laser system is responsive to the actuation of the laser actuator **222**. In one embodiment, the targeted tissues are inspected using the viewing fiber **202**.

In one embodiment, the dispenser **166**, the distal end **108** of the shaft **104**, and/or the balloon **110** are configured to provide substantially uniform transmission of the laser light **164**.

In one embodiment, the dispenser **166**, the distal end **108** of the shaft **104**, and/or the balloon **110** are configured to provide non-uniform transmission of the laser light to control the exposure of the target tissue to the laser light. In one embodiment, a coating is applied to the shaft **104** and/or the interior of the balloon **110** to control the transmission of the laser light there-through.

In one embodiment, the distal end **168** of the laser fiber **162** is moved along an arc and/or axially to another position relative to the shaft **104** and the balloon **110** to target other tissue within the cavity of the patient.

In one embodiment, a flow of fluid or gas is circulated through the balloon **110**. In one embodiment, the flow of fluid or gas is regulated responsive to a temperature signal from a temperature sensor **212**.

Following the completion of the ablation treatment, the balloon **110** is returned to its deflated state **124** and the balloon **110**, the shaft **104**, the laser fiber **162** and other components of the system (e.g., the viewing fiber **202**) are removed from the cavity. The disposable components can then be detached from the laser system **160**, the pump **144** and the viewing console **208**, removed from the applicator **102** and discarded.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

1. A laser ablation system configured to ablate targeted tissue of a patient, the system comprising:
- a shaft having a proximal end and a distal end with a bore;
- a cap;
- a balloon having a length extending between a proximal end of the balloon and a distal end of the balloon; and
- a laser fiber having a distal end comprising a light dispenser configured to deliver laser light through the balloon, wherein:
  - the balloon is attached to the distal end of the shaft when the distal end of the balloon is disposed between the cap and the bore,
  - the distal end of the shaft is disposed within the balloon and spaced distally from the proximal end of the balloon,
  - the balloon includes:
    - an inflated state, in which the balloon is shaped to conform to a cavity of a patient,
    - a central axis aligned with a longitudinal axis of the shaft, and
    - a variable transparency whereby the transmission of a laser light through the balloon is non-uniform along the central axis, and

an energy of the laser light transmitted from the light dispenser through the balloon to the targeted tissue varies due to the variable transparency of the balloon.

2. The system of claim **1**, wherein the balloon is shaped to conform to a uterine cavity of a patient.

3. The system of claim **1**, wherein the shaft comprises:

first and second openings at the distal end;

first and second ports at the proximal end;

a first fluid pathway connecting the first port to the first opening; and

a second fluid pathway connecting the second port to the second opening.

4. The system of claim **1**, further comprising a handheld unit configured to support the proximal end of the shaft and the laser fiber, the handheld unit comprising one or more laser fiber positioning components configured to rotate the laser fiber about a longitudinal axis of the laser fiber relative to the shaft, move the laser fiber along the longitudinal axis of the laser fiber relative to the shaft, and/or move the distal end of the laser fiber along an arc relative to the balloon.

5. The system of claim **1**, further comprising a laser system coupled to a proximal end of the laser fiber and configured to transmit laser light through the laser fiber and the light dispenser.

6. The system of claim **1**, wherein the balloon surrounds the light dispenser in a plane that extends through the light dispenser and is perpendicular to the longitudinal axis.

7. The system of claim **1**, wherein the distal end of the shaft is attached to the distal end of the balloon.

8. The system of claim **1**, wherein at least a portion of the shaft permits light to pass therethrough.

9. The system of claim **1**, wherein the distal end of the laser fiber is disposed within a portion of the shaft disposed within the balloon.

10. The system of claim **1**, wherein the light dispenser includes an etched section.

11. A method comprising:

powering a laser ablation system comprising:

a shaft having a proximal end, a distal end with a bore, and a longitudinal axis;

a cap;

a balloon having a length extending between a proximal end of the balloon and a distal end of the balloon; and

a laser fiber having a distal end comprising a light dispenser configured to deliver laser light through the balloon, wherein:

the balloon is attached to the distal end of the shaft when the distal end of the balloon is disposed between the cap and the bore,

the distal end of the shaft is disposed within the balloon and spaced distally from the proximal end of the balloon, and

the balloon includes:

an inflated state, in which the balloon is shaped to conform to a uterine cavity of a patient,

a central axis, and

a variable transparency whereby the transmission of a laser light through the balloon is non-uniform along the central axis;

feeding the distal end of the shaft into a uterus of a patient with the balloon in a deflated state;

inflating the balloon with a gas or fluid to the inflated state so that the balloon substantially conforms to the uterine cavity of the patient and engages the uterine walls;

transmitting the laser light through the laser fiber, the light dispenser, and the balloon;

exposing a tissue of the uterine walls to the laser light; and

ablating the tissue of the uterine walls with the laser light.

12. The method of claim **11**, wherein the distal end of the shaft is attached to the distal end of the balloon.

13. The method of claim **11**, wherein at least a portion of the shaft permits light to pass therethrough.

14. The method of claim **11**, further comprising inserting the distal end of the laser fiber into a portion of the shaft disposed within the balloon.

15. The method of claim **11**, wherein the light dispenser includes an etched section.

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